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10/585,553	07/06/2006	Jac-Kwan Hwang	20020-05USA	4188
7590 09/21/2009			EXAMINER	
JHK Law			RAO, SAVITHA M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,553	Applicant(s) HWANG ET AL.	
	Examiner SAVITHA RAO	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4 and 5 is/are pending in the application.
- 4a) Of the above claim(s) 1-2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/06/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-2 and 4-5 are pending.

Claims 1-2 are withdrawn from consideration as being drawn towards a nonelected invention.

Claims 4-5 are under consideration in the instant office action.

Election/Restrictions

Applicant's election with traverse of Group II (claims 4-5) in the reply filed on 08/06/2009 is acknowledged. The traversal is on the ground(s) that there is no undue burden in examining the two groups together as the antibacterial composition and the method of using such composition are linked so that examination of the claims of Group I would necessitate search of Group II claims.

Examiner finds the applicant's argument unpersuasive and maintains the restriction since as the Groups are patentably distinct and independent since they lack unity as set forth in the restriction requirement dated 07/07/2009 (pages 4-6). The subject matter clearly lacks unity of invention for the reasons given in the restriction requirement and, thus, the claims are directed to patentably distinct inventions and, thus, do not constitute overlapping subject matter that would result in a coextensive search.

Restriction for examination purposes as indicated is proper. Thereby the restriction requirement is still deemed proper and is therefore made FINAL.

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Claims under consideration in the current office action are claims 4-5. Claims 1-2 are withdrawn from consideration as being drawn to nonelected invention. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/06/2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable Sadhu et al. (Chem. Pharm. Bull. 51(5) 595-598 (2003) in view of Akamatsu et al. (Dermatology, 1998; 196: pages 82-85)

Sadhu et al disclose the activity of lignans which includes the instantly claimed macelignan isolated from *Leucas aspera* a medicinal plant of Bangladesh as prostaglandin inhibitors and antioxidants (abstract). Sadhu disclose that the whole plant is traditionally taken orally or applied topically for analgesic-antipyretic, anti-rheumatic, anti-inflammatory and antibacterial treatment etc (page 595, left col. 1st paragraph). Sadhu teaches compound LA-3 which is the instantly claimed compound mace lignan (see Fig 1 on page 596). Sadhu et al teaches that macelignan (LA-3) possess antioxidant activity with an IC₅₀ value of 35 μ M (page 596, left col. 2nd paragraph). Sadhu et al teaches that reactive oxygen and nitrogen species are closely related to inflammation and rheumatoid arthritis. Sadhu et al teaches that LA-3 (macelignan) 85together with other lignans may contribute through inhibition of the inflammatory process in the anti-inflammatory activity of *Leucas aspera* plant extract. As such macelignan would elicit anti-inflammatory activity because of its antioxidant property as demonstrated by Sadhu et al. Accordingly Sadhu et al provides explicit teachings of the anti-inflammatory activity of macelignan and suggests antibacterial activity of mace lignan. Sadhu et al teaches the oral and topical administration of *Leucas aspera* plant

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extract which comprises macelignan which renders the administration of macelignan to a subject obvious.

Sadhu et al. does not explicitly teach the method of treating acne by administration of the macelignan.

However, Akamatsu teaches that Acne is a chronic, inflammatory disease, in the progression of which *propionibacterium acnes* produces neutrophil chemotactic factors which releases various enzymes including lipases and proteases (page 82, left col. 1st paragraph). Akamatsu additionally teaches the involvement of neutrophil-derived reactive-oxygen species (ROS) in the irritation and destruction of the follicular wall, which is responsible for the inflammatory progression of acne (page 84, conclusion). As such Akamatsu provides an ordinarily skilled artisan motivation to treat Acne with anti-inflammatory agents and/or anti-oxidants.

In view of the foregoing reference it would have been prima facie obvious to one of ordinary skill in the art to develop a method of treating inflammatory disease such as acne comprising administering to a subject the instantly claimed lignan. Lignan compounds claimed in instant claim 5 were well known in the art at the time of the invention. Sadhu teaches that the instantly claimed lignan may contribute through inhibition of the inflammatory process in the anti-inflammatory activity of *Leucas aspera* plant extract and suggests that the plant *Leucas aspera* also possess antibacterial and antioxidant properties. An ordinarily skilled artisan would therefore be motivated to utilize macelignan for treatment of acne which is a known inflammatory disease characterized by activity of the bacteria *propionibacterium acnes* which facilitate

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production of reactive oxygen species (ROS). Sadhu's teachings that the instantly claimed macelignan possesses anti-inflammatory, anti-bacterial and anti-oxidant properties makes it an ideal candidate compound for treating acne. As such an ordinarily skilled artisan would have a reasonable expectation of success that mace lignan would provide a better treatment option for acne.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorman et al (Journal of Applied Microbiology, 2000, 88, 308-316) as evidenced by Woo et al (Phytochemistry, Volume 26, issue 5, 1987 pages 1542-1543, Abstract only).

Dorman et al teaches Antibacterial activity of plant volatile oils which include volatile oil of nutmeg (*Myristica fragrans*) (abstract). Dorman et al teaches that the volatile oil of nutmeg *M.fragrans* was equally effective against both Gram-positive and Gram-negative microorganism (page 309, Results section, 2nd paragraph). Table 1 on page 310; shows the inhibitory concentration of *Myristica fragrans* on several bacterial strains and shows clear inhibition of S.Aureus (see the penultimate bacteria in the table). The volatile extract of *Myristica fragrans* comprises of the instantly claimed compound macelignan as evidenced by the Woo et al abstract which shows that the instantly claimed lignan was isolated from *Myristica fragrans*. Dorman et al suggests that the tested plant products which includes the volatile oil of *Myristica fragrans* may be administered orally, to control a wide range of microbes since they appear to be effective against a wide spectrum of microorganisms.

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Accordingly, Dorman et al provides motivation to an ordinarily skilled artisan to test the active component of the nutmeg plant (*Myristica fragrans*) for its antibacterial properties since the oil extract of nutmeg displayed a broad spectrum of antibacterial property. It would have been prima facie obvious to one of ordinary skill in the art to develop a method of inhibiting bacteria such as *S.aureus* comprising administering to a subject the instantly claimed lignan. Lignan compounds claimed in instant claim 4 were well known in the art at the time of the invention. An ordinarily skilled artisan would have a reasonable expectation of success that the macelignan active ingredient of the nutmeg oil will display antibacterial effects since the oil comprising this lignan have been shown to possesses a broad spectrum of anti-bacterial activity against both gram negative and gram positive bacteria.

Conclusion

Claims 4-5 are rejected. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614